

### **REMARKS**

This Amendment responds to the Office Action dated October 19, 2005. Claims 31, 32 and 34-59 are pending after entry of the amendment. Of these, claims 51-53 are withdrawn from consideration pursuant to a restriction requirement. Claims 55 and 58 are generic to all species.

#### **Formal objection**

The Examiner objected to claim 55 on formal grounds. Claim 55 has been amended to address the Examiner's objection. All claims meet the formal requirements of 35 U.S.C. § 112.

#### **Rejections under 35 U.S.C. § 102**

The Examiner rejected claims 34-41, 43-47, 49, 50 and 54 under 35 U.S.C. § 102(e) as being anticipated by Stack et al. US 2005/0004681 ("Stack"). Independent claim 34 has been amended to recite the step of regulating the portion of food diverted to the intestinal bypass by adjusting a cross sectional lumen size of the adjustable intestinal pathway. Stack does not disclose this method step. Instead, Stack's device delivers all food leaving the stomach beyond the proximal portion of the small bowel. Stack never adjusts the size of the device pathway to divert a portion of the food to a bypass. Claim 34, and claims 35-41, 43-47, 49, 50 and 54 depending from claim 34, are therefore patentable over Stack under § 102(e).

The Examiner rejected claims 34-40 and 46-50 under § 102(e) as being anticipated by Bessler US 2004/0039452 ("Bessler"). Bessler's device does not perform the recited step of regulating the portion of food diverted to the intestinal bypass by adjusting a cross sectional lumen size of the adjustable intestinal pathway. Rather, Bessler discloses a gastric bypass through which *all* ingested food flows. Claim 34, and claims 35-40 and 46-50 depending from claim 34, are therefore patentable over Bessler under § 102(e).

The Examiner rejected claims 34-37, 41, 43, 46, 49, 50, 55, 57 and 58 under 35 U.S.C. § 102(e) as being anticipated by Gannoe et al. US 2004/0006351 ("Gannoe"). Gannoe describes a method of making a pouch within a stomach by using staples or other fasteners. The Gannoe device does not perform the step recited in claim 34 of regulating the portion of food diverted to the intestinal bypass by adjusting a cross sectional lumen size of the adjustable intestinal pathway.

Claim 34, and claims 35-37, 41, 43, 46, 49 and 50 depending from claim 34, are therefore patentable over Gannoe under § 102(e).

Likewise, Gannoe does not disclose the steps recited in claim 55 of connecting a first region of an intestinal tract to a second region of the intestinal tract with a bypass device; diverting a portion of food flowing from the first region to the second region through the bypass device; and permitting a remaining portion of the food flowing through the intestinal tract to flow from the first region to the second region through a natural portion of the intestinal tract. Claim 55, and claims 57 and 58 depending from claim 55, are therefore patentable over Gannoe under § 102(e).

The Examiner rejected claims 34-37, 46, 47, 49, 50 and 54-58 under 35 U.S.C. § 102(e) as being anticipated by Solomon et al. US 2004/0220516 ("Solomon"). Solomon fails to disclose the step recited in claim 34 of regulating the portion of food diverted to the intestinal bypass by adjusting a cross sectional lumen size of the adjustable intestinal pathway. In addition, while the Examiner has characterized Solomon elements 2 and 20 as forming "an adjustable pathway," these elements are merely inflatable anchors holding the device in place. Claim 34, and claims 35-37, 46, 47, 49, 50 and 54 depending from claim 34, are patentable over Solomon under § 102(e).

With respect to claim 55, Solomon shows in Figure 11 a device that connects the stomach with the intestines. Solomon does not disclose the recited method step of connecting *a first region of an intestinal tract* to *a second region of the intestinal tract* with a bypass device. Solomon's method of causing weight loss therefore differs from the method recited in claim 55. Claim 55, and claims 56-58 depending from it, are therefore patentable over Solomon under § 102(e).

#### Rejections under 35 U.S.C. § 103

The Examiner rejected claim 42 under 35 U.S.C. § 103(a) as being unpatentable over Stack in view of Solomon. Claim 42 depends from claim 34 through claims 41 and 36. As discussed above, neither Stack nor Solomon discloses or suggests, alone or in combination, the step recited in claim 34 of regulating the portion of food diverted to the intestinal bypass by adjusting a cross sectional lumen size of the adjustable intestinal pathway. Claim 42 is therefore patentable over Stack and Solomon under § 103(a).

The Examiner rejected claims 31, 47 and 54 under 35 U.S.C. § 103(a) as being unpatentable over Gannoe and Solomon. For purposes of this discussion, Applicant assumes the Examiner

intended to reject claim 32 under the same grounds. Claim 31 recites the steps of surgically creating an intestinal bypass with an adjustable opening, calculating a new bypass opening size, and changing bypass opening size to the new bypass opening size. As discussed above, neither Gannoe nor Solomon discloses or suggests these method steps. Gannoe describes a method of making a pouch within a stomach by using staples or other fasteners; there is no intestinal bypass, with or without an adjustable opening. Solomon Figure 11 shows a bypass connecting the stomach with the intestine. In addition, the Solomon device lacks an adjustable opening. Neither Gannoe nor Solomon calculate bypass opening sizes, and neither reference discloses the step of adjusting a bypass opening size. Claim 31, and claim 32 depending from it, are patentable over Gannoe and Solomon under 35 U.S.C. § 103(a).

Claims 47 and 54 depend from claim 34 and are patentable over Gannoe and Solomon for at least the reasons stated above with respect to claim 34.

New claim 59

Applicant has added a new claim 59 depending from claim 55. Claim 59 is allowable over the prior art of record for the reasons stated above with respect to claim 55.

**CONCLUSION**

Applicants submit that the instant application is in condition for allowance. Should the Examiner have any questions, the Examiner is requested to contact the undersigned attorney.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 32344-701.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Date: 2/21/06



James R. Shay, Reg. No. 32,062

650 Page Mill Road  
Palo Alto, CA 94304  
(650) 493-9300  
Customer No. 021971